

# Investor Overview

Cowen 39<sup>th</sup> Annual HealthCare Conference

March 2019

# Cautionary Note On Forward-Looking Statements

This presentation contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and we intend that such forward-looking statements be subject to the safe harbors created thereby.

Forward-looking statements include projections, statements about our future and those that are not historical facts. All forward-looking statements that are made in this presentation are subject to risks, uncertainties and other factors that could cause our actual results to differ materially. These are discussed in greater detail in our Annual Report on Form 10-K for the year ended December 31, 2018 and other reports we file with the SEC.

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# Executive Summary

## **WHO WE ARE:**

A diagnostics company based in Arizona, founded in 2012, with the vision of reducing the impact of Sepsis.

## **PROBLEM STATEMENT:**

Sepsis is a significant burden on the world's healthcare systems, causing hundreds of thousands of potentially avoidable deaths and costing \$27 billion each year in the U.S. alone.

## **OUR SOLUTION:**

Accelerate Pheno™ system uses proprietary technology to identify pathogens and report AST results needed to determine optimal antibiotic treatment in about 7 hours, saving 40 hours on average compared to conventional methods.

## **MARKET OPPORTUNITY / FUNDAMENTALS:**

First-mover advantage with high barriers to entry in a \$2B TAM. Razor/blade business model should support normalized 70% GM with significant FCF at scale, all while advancing our mission to save lives and reduce healthcare costs.

## **MARKET PENETRATION:**

Doubled commercially contracted installed base in Q4 with significant runway for growth.

# Sepsis Costs U.S. Hospitals an Estimated \$27B and Causes Hundreds of Thousands of Potentially Avoidable Deaths Each Year

## HUMAN COST

270,000 people die from Sepsis every year in the U.S.; more than from prostate cancer, breast cancer and AIDS combined.<sup>1,2</sup>

.....

Globally, Sepsis affects more than 30 million people and takes 8 million lives - including more than 3 million children each year.<sup>3,4,5</sup>

## HOSPITAL COST

Sepsis is the #1 cause for hospitalization in the U.S., costing more than \$27 billion each year<sup>6,7,8,9</sup>

.....

Sepsis is also the leading cause of hospital readmissions, resulting in more than \$2 billion in costs each year.<sup>6</sup>

**Antibiotic Susceptibility Testing (AST) is the only way to know which drug will work**  
Clinicians today still wait multiple days for this lengthy test

<sup>1</sup> Rhree C, et al., JAMA. 2017; <http://jamanetwork.com/journals/jama/fullarticle/2654187>

<sup>2</sup> Heron M, CDC. 2017; [https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67\\_06.pdf](https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_06.pdf)

<sup>3</sup> Dungani S, et al., J Infect. 2016; [http://www.journalofinfection.com/article/S0163-4453\(17\)30193-7/pdf](http://www.journalofinfection.com/article/S0163-4453(17)30193-7/pdf)

<sup>4</sup> Fleischmann A, Am J Respir Crit Care Med 2016; <http://www.atsjournals.org/doi/full/10.1164/rccm.201504-0781OC>

<sup>5</sup> Kissoon N, et al., J Infect. 2015; [http://www.journalofinfection.com/article/S0163-4453\(15\)00109-7/fulltext](http://www.journalofinfection.com/article/S0163-4453(15)00109-7/fulltext)

<sup>6</sup> Torio C, et al., HCUP 2016; <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf>

<sup>7</sup> McDermott K, et al., HCUP 2017; <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb225-Inpatient-US-Stays-Trends.jsp>

<sup>8</sup> Tozzi J, Bloomberg News 2017; <https://www.bloomberg.com/news/articles/2017-07-14/america-has-a-27-billion-sepsis-crisis>

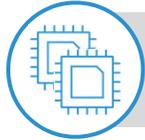
<sup>9</sup> Arefian, Habibollah et al., J Infect. 2017; [http://www.journalofinfection.com/article/S0163-4453\(16\)30288-2/fulltext](http://www.journalofinfection.com/article/S0163-4453(16)30288-2/fulltext)

# We Cut the Time Clinicians Have to Wait for AST by > 75%

Novel Tech Creates  
High Barriers to Entry



Custom Machine Learning Algorithms



Custom CUDA Computing Platform



Proprietary Sample Prep Automation



Patented Optics and Chemistry

## AST results and pathogen ID *days* faster

ACCELERATE  
*pheno*<sup>™</sup>



The only FDA cleared solution for quantitative AST directly from positive blood cultures

Accelerate Pheno<sup>™</sup> system



**40+ hrs saved<sup>1</sup>**

Conventional Methods



0 20 40

■ ID

■ AST

<sup>1</sup> Lutgring JD, Bittencourt C, McElvania TeKippe E, et al. Evaluation of the Accelerate Pheno System: Results from Two Academic Medical Centers. J Clin Microbiol 2018; 56.

# Faster AST Results From Accelerate Pheno™ System Are Making a Difference

## Improved Patient Outcomes

- Reduction in mortality<sup>1</sup>
- Reduction in morbidity
- Less unnecessary antibiotic exposure
- Less time in the hospital

Indiana University study found approx. 84% of patients could have had therapy optimized earlier had AXDX AST been available<sup>2</sup>

## Hospital Savings

- 3-day reduction in hospital length of stay, on average<sup>3</sup>, representing \$6,000 savings per patient or a 30x ROI per test<sup>4</sup>
- Further potential savings by reducing rates of resistance and readmissions

University of Arkansas for Medical Sciences study reported 3-day reduction in average hospital length of stay with AXDX<sup>4</sup>

<sup>1</sup> Data generated and presented by Laboratory Services, University Healthcare System, Augusta, GA

<sup>2</sup> Schneider J., et al. Rapid Identification and Antimicrobial Susceptibility Testing ...and its Potential Clinical Impact; Presented at IDWeek 2018.

<sup>3</sup> Dare R, McCain K, Lusardi K et al. Impact of Accelerate Pheno™ ...on Laboratory and Clinical Outcomes in Bacteremic Patients...Presented at IDWeek 2018

<sup>4</sup> Estimates based on 1999 - 2016 AHA Annual Survey reported by the Kaiser Family Foundation.

# Faster AST Results From Accelerate Pheno™ system Are Making a Difference

1. A large southeastern regional medical center recently acquired the Accelerate Pheno™ system & went clinically live
2. A patient receiving a kidney transplant (~\$400,000<sup>1</sup>), suspected of contracting a serious infection during recovery, was one of the first patients tested on Pheno
3. Due to the life-threatening infection, broad-spectrum antibiotics were initiated, including two antibiotics known to cause kidney damage
4. Pheno's unique AST capabilities identified several antibiotic alternatives—with fewer toxic side effects—about two days faster than current standard of care
5. The clinicians de-escalated from broad-spectrum therapy to one targeted antibiotic, preserving the transplanted kidney and allowing the patient to make a full recovery



<sup>1</sup> Bently T, Phillips S, et. al. 2017 U.S. organ and tissue transplant cost estimates and discussion. Milliman Research Report. <http://milliman.com/transplant-report> [accessed Jan 2019]

# Competitive Overview



*“...even with standard stewardship interventions, multiplex molecular panel testing did not affect antimicrobial prescribing, although results of other kinds of testing — namely, gram staining and antimicrobial susceptibility testing — were able to induce physicians to alter course appropriately.” – study authors, Mayo Clinic, Dec 2018*

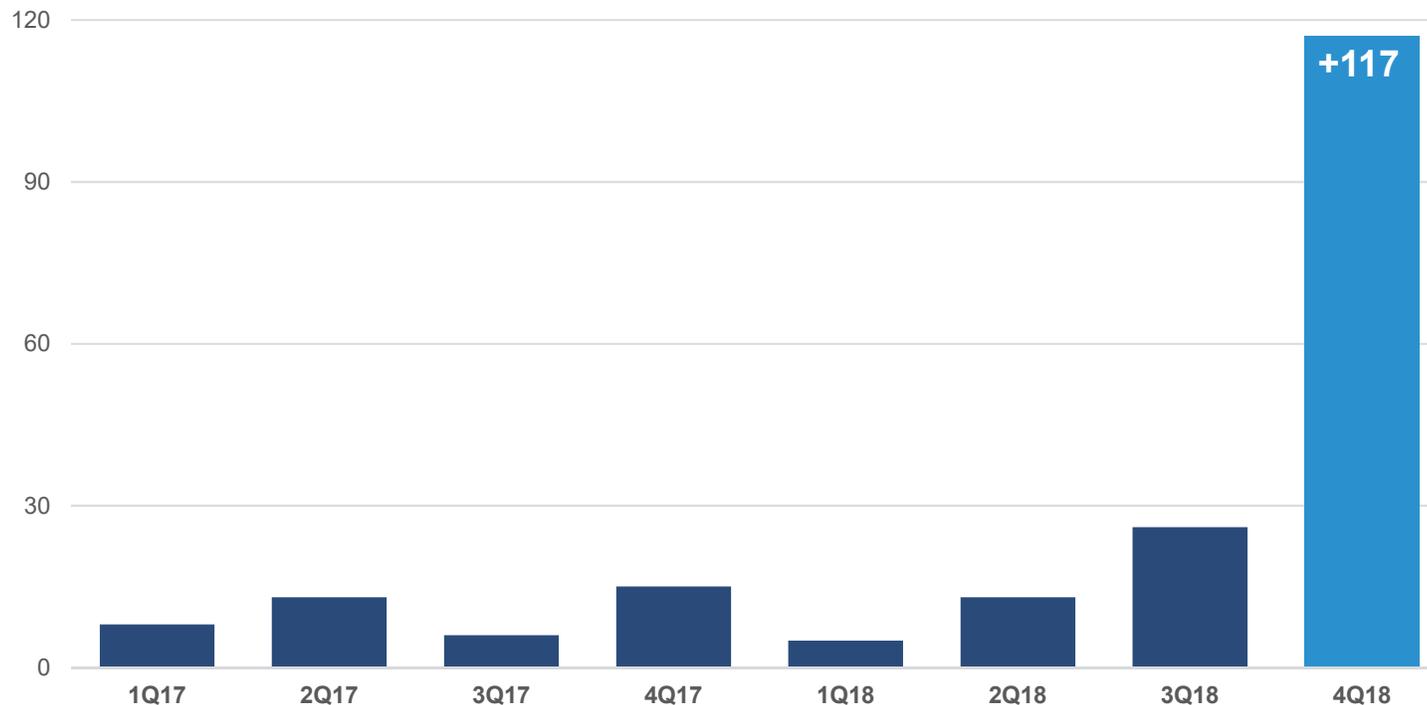
<sup>1</sup> Tseng A, Kasule S, Rice F, Mi L, Chan L, Seville M, Grys T; Open Forum Infectious Diseases, Volume 5, Issue 12, 1 December 2018

# Review of 2018 U.S. Commercial Progress

	Q1 2018	Q2	Q3	Q4
<b>Improving Sales Cycle</b>	Revised sales process to extend beyond the lab	Gained access to additional GPOs		ARLG completed study enrollment <i>(Mayo, UCLA)</i>
	Expanded commercial sales team	UAMS Study <i>(3-day LOS)</i>		
<b>Removing Capital Constraints</b>				Added reagent rental acquisition option <i>(Customers begin bypassing evaluations)</i>
<b>Reducing Time to Clinical Go-Live</b>	Streamlined verification protocol	Built out dedicated LIS and clinical implementation teams		Launch of Customer Implementation Program

# Encouraging 4Q18 U.S. Commercial Placement Trajectory

## U.S. Quarterly Net Additions to Commercially Contracted Instruments:



**More than doubled commercial placement installed base in 4Q18**

- Cumulative U.S. commercial placements of: 209
- Q4 2018 additions consisted of a mix of converted evaluations and direct placements (customers bypassing evaluation)

# Commercial Placements Span all Key U.S. Hospital Segments

## Half of the 2018-19 Top 10 Children's Hospitals<sup>1</sup>

Children's Hospital of Philadelphia

Texas Children's Hospital

Children's National Medical Center

Children's Hospital Los Angeles

Ann and Robert H. Lurie Children's  
Hospital of Chicago

## Top Cancer Hospitals<sup>1</sup>

- University of Texas MD Anderson Cancer Center
- St. Jude Children's Research Hospital
- Moffitt Cancer Center

## Academic Centers & Government

- University of Arkansas for Medical Sciences
- University of Iowa Hospital & Clinics
- Madigan Army Medical Center
- VA St. Louis Healthcare System

## Integrated Health Networks

- Adventist Health
- Univ of Colorado Health (UCHealth)
- Mercy Health
- Baycare Health System
- MedStar Health

## Regional Hospitals and Health Systems

- University Health Care System
- Peninsula Regional Medical Center
- Hamilton Health Care System
- South Nassau Communities Hospital
- Peterson Regional Medical Center

<sup>1</sup> Rankings based on 2018-19 US News & World Report

# 2018 EMEA Commercial Update

**EMEA continues to evolve though remains behind the U.S. due to tenders and pending health-economic studies and reimbursement decisions**

- Cumulative EMEA commercial placements of 71—including 16 net 4Q18 additions
- Focusing direct sales team efforts in highest opportunity markets
- Distribution network continues to expand EMEA breadth into Eastern EU and Middle Eastern markets; currently delivering strong capital mix
- Longer than expected time-to-annuity for tender contracts
- Expecting increases in assay utilization over the intermediate timeframe



# 2019 Focus Areas

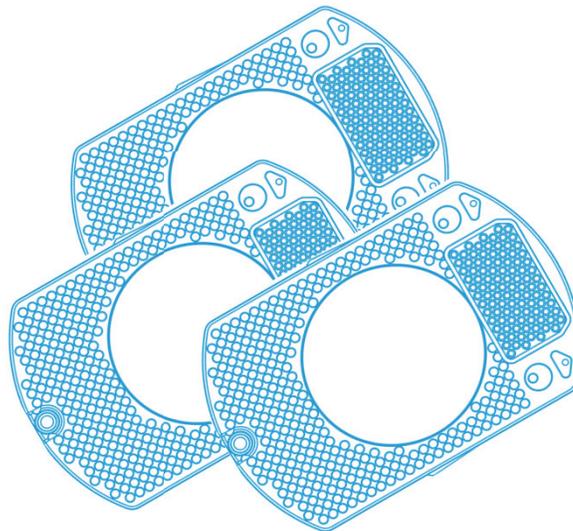
## Market Penetration

*Increase the number of new customers & commercially contracted instruments*



## Improve Time to Annuity

*Drive clinical go-lives and test kit utilization*

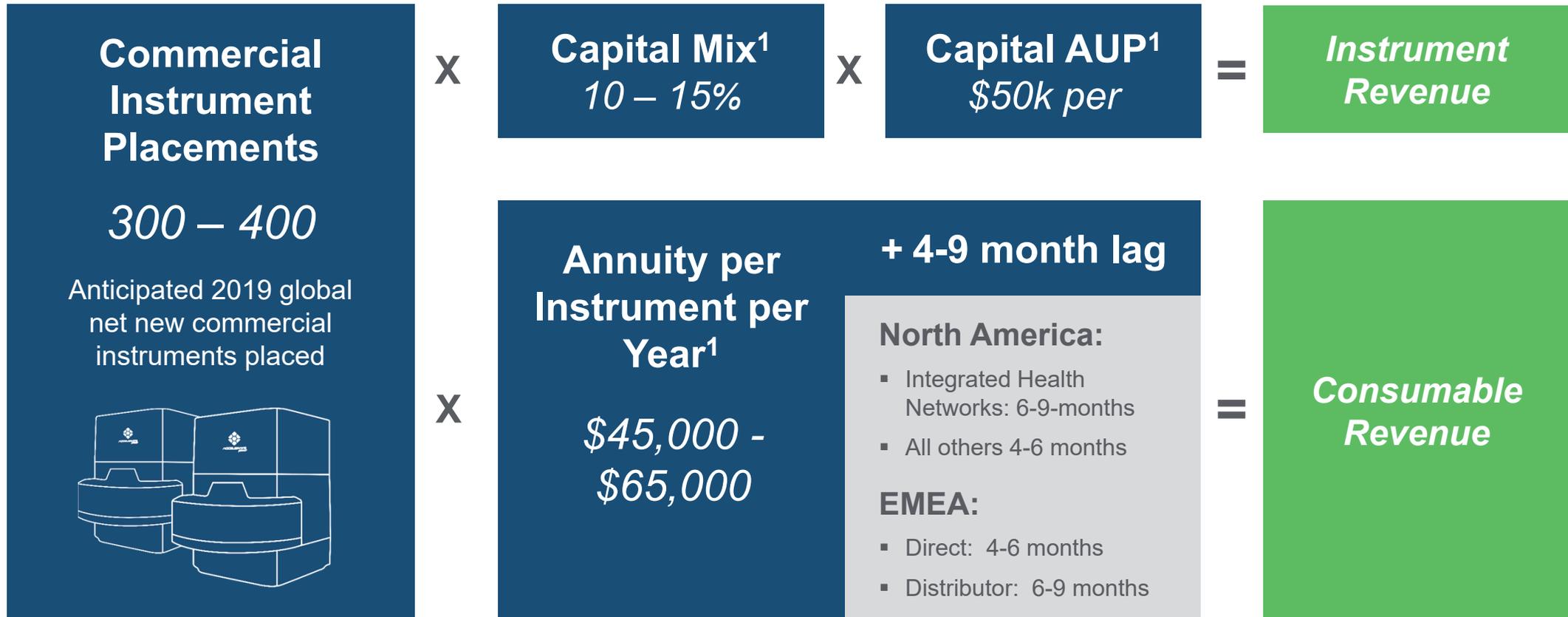


## Respiratory & China

*Complete trial for severe pneumonia kit and begin registration trial for China*



# Global Outlook: 2019 Expectations



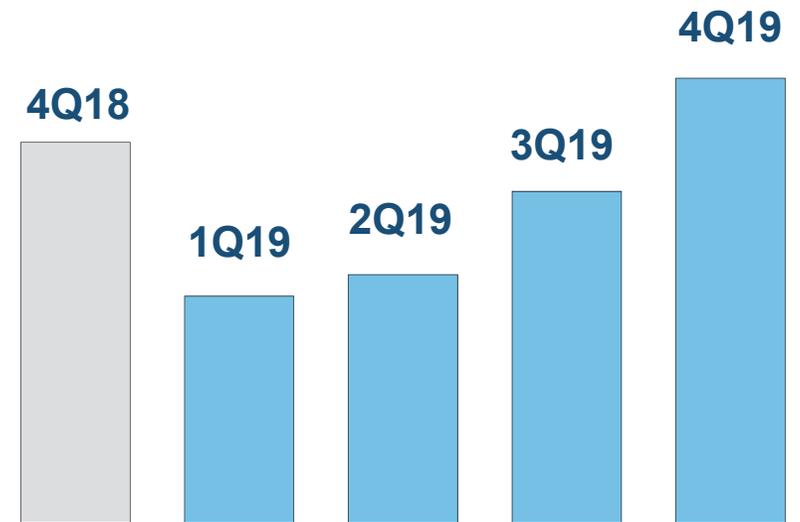
<sup>1</sup> Based on 2018 commercial customers and anticipated 2019 annuity per instrument

# Global Outlook: 2019 Quarterly Cadence

Step-down in 1Q19 commercial placements from 4Q19, but significant growth over 1Q18

Lighter 1H19 capital revenue due to hospital budget timing

Expect 2H19 revenue ramp, as recently contracted commercial instruments complete verification/implementation process and begin generating normalized test kit utilization



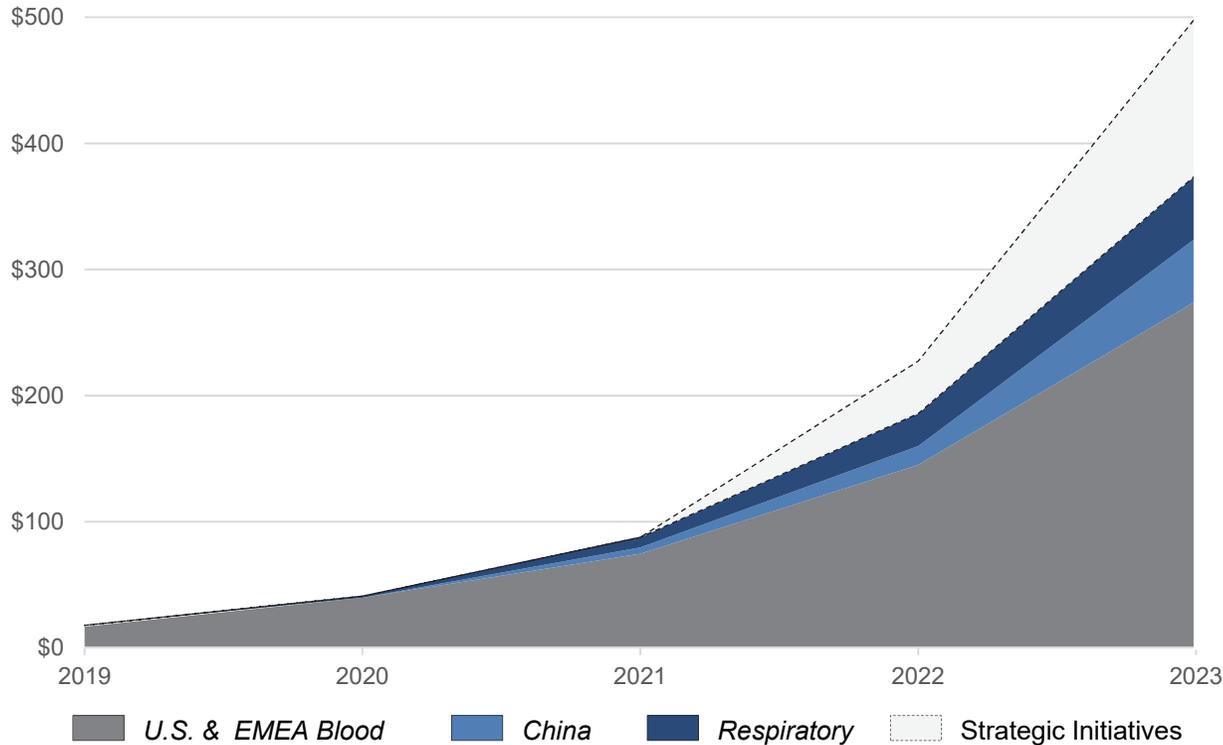
*Shown for illustrative periodization purposes*

<sup>1</sup> Based on 2018 commercial customers and anticipated 2019 annuity per instrument

# Strategic Plan to Address \$2B Market Opportunity

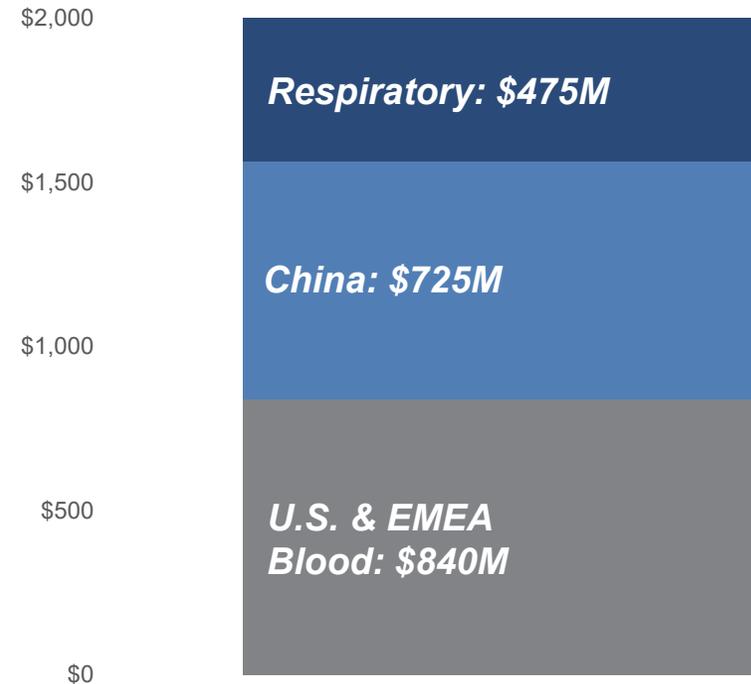
## Revenue Opportunity<sup>1</sup>

\$ in Millions



## Addressable Market<sup>2</sup>

\$ in Millions



<sup>1</sup> Based on management estimates of commercial timing and market penetration

<sup>2</sup> Based on management estimates market size

# Blood: Building a Strong Foundation

## Strategy

### Focused commercial execution & expansion:

- Expand sales teams to accelerate rate of adoption once target salesforce productivity levels are achieved

### Pursue NTAP reimbursement:

- Accelerate Pheno™ system outcomes uniquely position Accelerate to receive New Technology Add-On Payments (NTAP) from the Centers for Medicare and Medicaid Services (CMS)

## Catalysts

- Achieve 2019 targets for penetration
- New clinical outcomes data releases - *H1 & H2 2019 (details on following slide)*
- Submit for NTAP reimbursement - *H2 2019*
- Approval for NTAP reimbursement - *H2 2020*

## Opportunity

U.S. + EMEA Addressable Market Opportunity

4.2M<sup>1</sup>  
bloodstream  
infection tests

X

\$200<sup>2</sup>  
AUP

=

\$840M  
Market Opportunity

<sup>1</sup> Management estimate of market size

<sup>2</sup> Consumable AUP based on current commercial trends

# Prospective Outcomes Data Releases

RCT <sup>1</sup> Study	Primary Endpoints	Secondary Endpoints	Commercial Impact	Timing
<b>ARLG (MAYO/UCLA)</b>	Time to first antibiotic modification	Mortality, LOS, acquisition of HAIs, time to antibiotic escalation	<i>Establish foundation for clinical action enabled by AXDX. Amplify prior outcomes data.</i>	<b>1H19</b>
<b>Genotypic versus Phenotypic</b>	Duration of broad spectrum antimicrobial therapy	Mortality, LOS, antibiotic toxicity	<i>Clinical impact of AXDX compared with genotypic (ID only) platform</i>	<b>2H19</b>
<b>Emergency Dept. Populations</b>	Composite clinical outcome (LOS, ICU admission, antibiotic toxicity)	Antibiotic escalation, de-escalation, mortality, acquisition of HAIs	<i>Ability of AXDX to impact emergency department populations for early discharge, e.g. LOS</i>	<b>2H19</b>

<sup>1</sup> Randomized controlled trial (or randomized control trial; RCT) is a type of scientific (often medical) experiment which aims to reduce bias when testing a new treatment.

# China: Geographic Expansion

## Strategy

### Significant market opportunity with attractive hospital economics:

- Estimated 2.3M<sup>1</sup> bloodstream infection tests in China alone, with double-digit growth per annum
- Unique reimbursement opportunity with FISH-based technology
- Completed reimbursement and market assessment study along with review of National Medical Products Administration (NMPA) registration partners
- Establishing strong network of provincial KOLs to champion the technology

## Catalysts

- Initiate NMPA clinical trial - *2H 2019*
- NMPA trial completion - *1H 2020*
- Commercial launch and first patient sample tested - *1H 2021*

## Opportunity

China +BC Addressable Market Opportunity

2.3M<sup>1</sup>  
bloodstream  
infection tests

X

~\$315<sup>2</sup>  
AUP

=

\$725M  
Market  
Opportunity

<sup>1</sup> Management estimate of market size at commercial launch

<sup>2</sup>AUP based on ~\$315 government reimbursement per test, exclusive of distributor margin

# Respiratory: High-Value Test for Bacterial Pneumonia to Leverage Existing Installed Base

## Strategy

- Hospital acquired pneumonias and other serious bacterial pneumonias are among the most costly healthcare conditions with high mortality rates
- Inadequacy of current methods provides opportunity to create a new standard of care
- Commercial strategy focused on pulmonologists and based around the potential for improved clinical outcomes

## Catalysts

- Clinical trial start – *1H 2019*
- Global Clinical Outcomes study start - *2H 2019*

## Opportunity

U.S. + EMEA Addressable Market Opportunity

**1.9M**  
*ETA & BAL*  
*Samples Tested*

X

**~\$250<sup>1</sup>**  
*AUP*

=

**\$475M**  
*Market*  
*Opportunity*

<sup>1</sup>AUP based on based on initial pricing assumptions; pending clinical outcomes study

# Addressing Unmet Clinical Needs in Microbiology

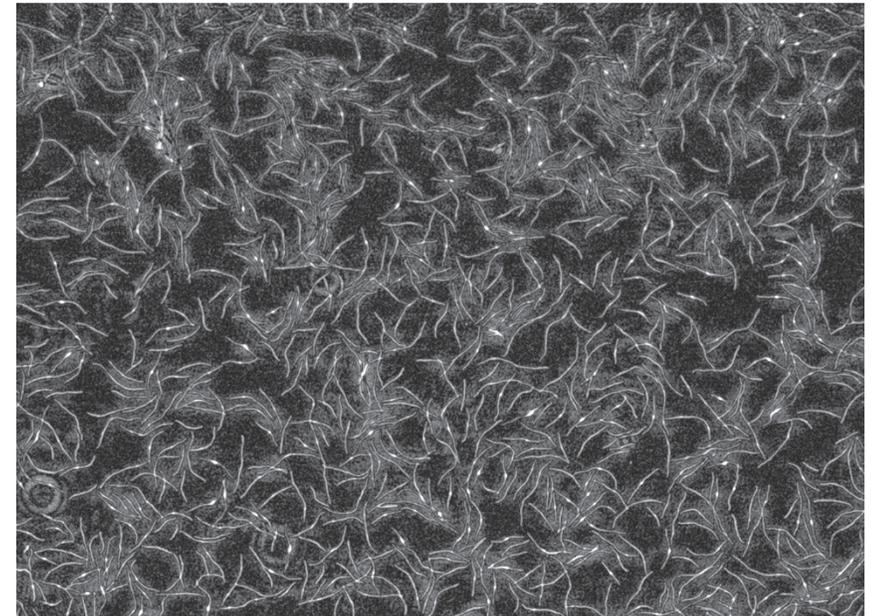
## Expanding offerings to meet unmet clinical demands within microbiology

### Additional kit menu offerings for the Accelerate Pheno™ system

- Menu expansion through Pharma partnerships
- Additional high-acuity sample types for the Accelerate Pheno™ system

### Scalable rapid pathogen detection and susceptibility platform

- Modular and scalable for small and very large centralized laboratories
- Market expansion with the addition of higher volume specimen types; potential inclusion of outpatient samples
- Enhanced capabilities in TAT, LoD, and direct sample handling



Susceptible *Klebsiella* spp. to Cefepime - AST image taken with prototype next generation AST platform

# Closing

Sepsis poses significant challenges to global healthcare systems—our customers are experiencing improved patient outcomes and material cost reductions compared to current standard of care.

2018 brought many challenges, prompting us to refine our commercial approach: making material changes to the sales team, arming our salespeople with more robust clinical data, and addressing a primary hurdle to adoption through our reagent rental program.

We are confident that our strong Q4 commercial placements show early evidence that these changes to our strategy are working, and we are committed to building upon that progress in 2019.

Accelerate Diagnostics, Inc. is well-positioned for leadership in this high-impact \$2B market and has the opportunity to continue improving patient outcomes worldwide through geographic expansion and ongoing menu development.